



UNITED STATES PATENT AND TRADEMARK OFFICE

DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE
BOARD OF PATENT APPEALS AND INTERFERENCES
BOX INTERFERENCE, WASHINGTON, D.C. 20231

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MAILED

OCT - 7 2005

PAT. & T.M. OFFICE
BOARD OF PATENT APPEALS
AND INTERFERENCES

Applicants: Aronhime et al.
Application No.: 09/997,126
Filed: 11/29/01
For: Novel crystal forms of
atorvastatin hemi-calcium and processes
for their preparation as well as novel
processes for preparing other forms

The above-identified application or patent has been forwarded to the Board of Patent Appeals and Interferences because it is adjudged to interfere with another application or patent. An interference has been declared. The interference is designated as No. 105,384.

Notice is hereby given the parties of the requirement of the law for filing in the Patent and Trademark Office a copy of any agreement "in connection with or in contemplation of the termination of the interference." 35 U.S.C. § 135(c).

Fred E. McKelvey
Senior Administrative Patent Judge

INTERFERENCE DIGEST

Interference No. 105,384

Paper No.

Name: Judith Aronhime et al.

Serial No.: 09/997,126

Patent No.

Title: Novel crystal forms of atorvastatin hemi-calcium and processes for their preparation as well as novel processes for preparing other forms

Filed: 11/29/01

Interference with Byrn et al.

DECISION ON MOTIONS

Administrative Patent Judge, _____ Dated, _____

FINAL DECISION

Board of Patent Appeals and Interferences, _____ Dated, _____

Court, _____ Dated, _____

REMARKS

Mail Stop Interference
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Filed 7 October 2005

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

STEPHEN ROBERT BYRN, DAVID ANDREW COATES,
KAREN SUE GUSHURST, JOSEPH FRANCIS KRZYZANIAK,
ZHENG JANE LI, HENRY GRANT MORRISON II,
AERI PARK and PETINKA IVANOVA VLAHOVA,

Junior Party
(Patent 6,605,729 B1),

v.

MAILED

OCT - 7 2005

PAT. & T.M. OFFICE
BOARD OF PATENT APPEALS
AND INTERFERENCES

JUDITH ARONHIME, RAMY LIDOR-HADAS, VALERIE NIDDAM,
REVITAL LIFSHITZ and GUY SAMBURSKY,

Senior Party
(Application 09/997,126).

Patent Interference No. 105,384-McK
Technology Center 1600

DECLARATION - Bd.R. 203(d)

Part A. Declaration of interference

An interference is declared (35 U.S.C. § 135(a)) between the above-identified parties. Details of the application, patent, count and claims designated as corresponding or as not corresponding to the count appear in Parts E and F of this DECLARATION.

Part B. Judge managing the interference

Administrative Patent Judge McKelvey has been designated to manage the interference. 37 CFR § 41.104(a) [Bd. R. 104(a)].

Part C. Standing order

A Trial Section STANDING ORDER (Paper 2) accompanies this DECLARATION. The STANDING ORDER applies to this interference.

Part D. Initial conference call

A telephone conference call to discuss the interference is set for 1:30 p.m. (1330 hours Eastern Time) on Monday, 21 November 2005 (the Board will initiate the call).

No later than two business days (i.e., Thursday, 17 November 2005) prior to the conference call, each party shall file and serve by facsimile (STANDING ORDER ¶ 4.5) a list of the motions (Bd. R. 120; Bd. R. 204; STANDING ORDER ¶ 26) the party intends to file.

A sample schedule for taking action during the motion phase appears as Form 2 in the STANDING ORDER. Counsel are encouraged to discuss the schedule prior to the conference call and to agree on dates for taking action. A typical motion period lasts approximately eight (8) months. Counsel should be prepared to justify any request for a shorter or longer period.

Part E. Identification and order of the parties

Junior Party

Named inventors: Stephen Robert Byrn
West Lafayette, IN

David Andrew Coates
West Lafayette, IN

Karen Sue Gushurst
Lafayette, IN

Joseph Francis Krzyzaniak,
Pawcatuck, CT

Zheng Jane Li
Quaker Hill, CT

Henry Grant Morrison II
Lafayette, IN

Aeri Park
West Lafayette, IN

Petinka Ivanova Vlahova
Lafayette, IN

Patent: U.S. Patent 6,605,729 B1
issued 12 August 2003
based on application 10/184,669
filed 28 June 2002

Title: Crystalline forms of [R, - (R*, R*)] - 2 - (4 - fluorophenyl) - β , δ - dihydroxy - 5 - (1 - methylethyl) - 3 - phenyl - 4 - [(phenylamino) carbonyl] - 1H - pyrrole - 1 - heptanoic acid calcium salt (2:1)

Assignee: Warner-Lambert Company

Accorded Benefit: Provisional application 60/302,049
filed 29 June 2001

Senior Party

Named Inventors: Judith Aronhime, Israel
Ramy Lidor-Hadas, Israel
Valerie Niddam, Israel
Revital Lifshitz, Israel
Guy Sambursky, Israel

Application: Application 09/997,126,
filed 29 November 2001

Title: Novel crystal forms of atorvastatin
hemi-calcium and processes for
their preparation as well as novel
processes for preparing other forms

Assignee: Teva Pharmaceutical Industries Ltd

Accorded Benefit: Provisional application 60/267,897,
filed 09 February 2001¹

1 Aronhime also claims priority based on the following provisional applications:

- (1) provisional application 60/250,072, filed 30 November 2000,
- (2) provisional application 60/281,872, filed 05 April 2001,
- (3) provisional application 60/312,144, filed 13 August 2001 and
- (4) provisional application 60/326,529, filed 01 October 2001.

If Aronhime thinks that it is entitled to benefit for the purpose of priority of one or more of these provisional applications, it may list a motion for benefit when it submits its motions list. 37 CFR § 41.204(b) (2005); 69 Fed. Reg. 50019 (Aug. 12, 2004). The files of these provisional applications are being maintained with the records of the interference; copies may be ordered directly with the board.

The senior party is assigned exhibit numbers 1001-1999.

Bd. R. 154(c)(1).

The junior party is assigned exhibit numbers 2001-2999.

Bd. R. 154(c)(1).

The senior party is responsible for initiating settlement discussions. STANDING ORDER ¶ 18.

Part F. Count and claims of the parties

Count 1

A crystalline Form VIII atorvastatin hemi-calcium and solvates thereof characterized by a powder X-ray diffraction pattern generated using CuK_α radiation with peaks at

4.8
5.2
8.0
9.2
9.6
19.0
20.0
24.0 and
29.0

± 0.2 degrees two-theta

or

a crystalline Form X atorvastatin or a hydrate thereof having an X-ray powder diffraction containing the following 2θ values measured using CuK_α radiation:

4.7
5.2
5.8
6.9
7.9
9.2
9.5
10.3 (broad)
11.8
16.1
16.9
19.1
19.8
21.4
22.3 (broad)
23.7 (broad)
24.4 and
28.7.

The claims of the parties are:

Byrn: 1-15

Aronhime: 147-166

The claims of the parties which correspond to Count 1 are:

Byrn: 6

Aronhime: 147-166

The claims of the parties which do not correspond to Count 1, and therefore are not involved in the interference, are:

Byrn: 1-5 and 7-15

Aronhime: None

Part G. Heading to be used on papers

The heading in STANDING ORDER Form 1 must be used on all papers filed in this interference. See STANDING ORDER ¶ 7.2.1. The administrative patent judge and parties must be indicated as follows:

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

STEPHEN ROBERT BYRN, DAVID ANDREW COATES,
KAREN SUE GUSHURST, JOSEPH FRANCIS KRZYZANIAK,
ZHENG JANE LI, HENRY GRANT MORRISON II,
AERI PARK and PETINKA IVANOVA VLAHOVA,

Junior Party
(Patent 6,605,729 B1),

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JUDITH ARONHIME, RAMY LIDOR-HADAS, VALERIE NIDDAM,
REVITAL LIFSHITZ and GUY SAMBURSKY,

Senior Party
(Application 09/997,126).

Patent Interference No. 105,384--McK
Technology Center 1600

Part H. Order form for requesting file copies

When requesting copies of files, use of STANDING ORDER Form 4 will greatly expedite processing of the request. Please attach a copy of Part E of this DECLARATION with a hand-drawn circle around the patents and applications for which a copy of a file wrapper is requested.

Part I. Required paragraph for affidavits and declarations

The Board has recently experienced a rash of cases in which a witness has belatedly advanced reasons why he or she would be unable to appear for cross examination at a reasonable time and place in the United States. Consequently, the Board is requiring the following paragraph to be included on the signature page of all affidavits (including declarations) filed in this case to prevent surprise and hardship to the party relying on the testimony of the witness:

In signing this affidavit/declaration, I recognize that the affidavit/declaration will be filed as evidence in a contested case before the Board of Patent Appeals and Interferences of the United States Patent and Trademark Office. I also recognize that I may be subject to cross examination in the case and that cross examination will take place within the United States. If cross examination is required of me, I will appear for cross examination within the United States during the time allotted for cross examination.

/Fred E. McKelvey/

FRED E. MCKELVEY,
Senior Administrative Patent Judge

07 October 2005
Alexandria, VA

² As part of Board efforts under the Government Paperwork Elimination Act, signatures on papers originating from the Board are being phased out in favor of a completely electronic record. Consequently, in this case papers originating at the Board will not have signatures. The signature requirements for the parties have not changed. See, e.g., 37 CFR § 10.18.

Enc (there is no Form PTO-850):

STANDING ORDER (Paper 2)
DVD program
e-filing program
U.S. Patent 6,605,729 B1
Claims 147-166 of application 09/997,126
Specification, abstract and drawings (as filed)
of application 09/997,126
Oath of application 09/997,126
Specification, oath, abstract and drawings (as filed)
of application 10/860,084
Claims of application 10/860,084
Request under 37 CFR § 1.607 for declaration of an
interference filed 28 July 2004 in application
09/997,126
Bibliographic data for applications 10/860,084 and
09/997,126 and 10/184,669

Revised January 2005

cc (via overnight delivery) :

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